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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,715	02/05/2004	Gretchen Frantz	P5035R1	8324

9157 7590 11/03/2005

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EXAMINER	
YAO, LEI	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,715	FRANTZ ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed on 8/29/05 to the previous Non-Final Office Action (5/4/05) is acknowledged and has been entered.

Claims 1-16 have been cancelled. Claims 17-26 are pending and under consideration.

The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.

Response to Arguments

Rejection under 35 USC § 101 and 112 first paragraph

The rejections of claims 17-26 under 35 U.S.C. 101 and 112 first paragraph because the claimed invention is directed to non-statutory subject matter, not supported by either a specific, substantial, and credible asserted utility, and one skilled in the art clearly would not know how to use the claimed invention is maintained for the reasons of record in the prior Office Action (5/4/05, page 2-5).

The response filed 8/29/05 has been carefully considered but is deemed not to be persuasive.

The applicant on page 7 first agree that there are individual, specific instances where a correlation between the level of mRNA and the level of protein expressed from that mRNA in a particular cell type does not appear to exist. Then, applicants argue that it is widely known and well accepted in the scientific research community that there is a strong, general correlation between the amount of mRNA in a particular cell type and the amount of protein expressed from that mRNA for any particular gene of interest. Applicants further argue that the gene expression chips for measuring the gene expression in a sample at the mRNA level is useful in the biotechnology research industry, that it is more likely than not informative of the expressed protein level.

These arguments have been carefully considered, but are deemed not to be persuasive. First, applicants have not demonstrated that the correlation between level of mRNA and the level of protein expressed from that mRNA in uterine cells exists in the instant case. It is well accepted in the art that biological function resulting from the expression of particular gene is due to the level of the protein, not the level of the mRNA encoding the protein, in the tissues. The gene expression chip for detection of

mRNA provides just preliminary information for the expression of the particular gene at message levels, which has to be confirmed by the correlation the level of protein in the particular tissue in order to claim the biological effect by said protein. It is acknowledged in the art that control of gene expression can occur at multiple stages and that production of RNA cannot inevitably be equated with production of protein (Levin et al., Gene VI, chapter 29, page 847, column 2). Greenbaum et al., further teach that as mRNA is eventually translated into protein, one might assume that there should be some sort of correlation between the levels of mRNA and that of protein. Alternatively, there may not be any significant correlation, which, in itself, is an informative conclusion (page 117.1, column 1). After detailed analysis of the reasons for lack of correlation between the levels of mRNA and that of protein (entire document), Greenbaum et al., conclude that to be fully able to understand the relation between mRNA and protein abundances, the degradation, the dynamic processes involved in protein synthesis and degradation have to be better understood; is the protein level changing because of a change in the rate of protein synthesis, or mRNA, or protein turnover? (page 117.6, figure 2, column 2, para 2). Therefore, undue experimentations for ensuring the level of the protein in the cells or tissues are absolutely necessary for using that protein as a biomarker for detecting or diagnosing for the uterine cancer.

Secondly, applicants are reminded that instant set of claims is drawn to a method of binding an antibody to a human uterine cell that expresses said protein shown in SEQ ID NO: 6. The disclosure does not provides any evidence either to show the level of the protein in uterine tumor and normal uterine tissue or that an antibody for the protein (SEQ ID NO: 6) could bind to the uterine tumor or normal uterine tissues. One of ordinary skill in the art would not have a reasonable expectation of success to use the claimed invention.

Third, 35 U.S.C. 101 emphasize that the claimed invention needs to be supported by either a specific, substantial, and credible asserted utility or a well established utility. 35 U.S.C.112 first paragraph requires the claimed invention would allow one of skill in the art to use the invention without undue experimentation. The instant disclosure neither provides the claimed antibody, which specifically binds to human uterine cells, nor the level of the protein (SEQ ID NO:1), which is correlated with the level of mRNA in the human uterine cell. In the absence of any disclosed relationship between the

claimed antibody to protein (SEQ ID NO: 6) and any disease or disorder, any information obtained in an effort to establish a differential expression pattern would constitute further research on establishing a specific, substantial, and credible utility for the method reliant on the presence of SEQ ID NO: 6 in uterine cells. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing". Therefore, without objective evidence that the binding of an antibody to SEQ ID NO: 6 expressed on a cell is indicative of some pathological state, the instant claims lack a specific, substantial, and credible asserted utility and one skilled in the art clearly would not know how to use the claimed invention.

In addition, declaration submitted by Dr. Paul Polakis is acknowledged. In the Declaration, Dr. Polakis states that using microarray analysis, applicants have identified 200 transcripts that are present in human tumor cells at significantly higher levels than in corresponding normal human cells. Dr. Polakis then states antibodies to 30 of the tumor antigen are generated and bind to these differentially expressed gene transcripts and quantitatively determine the levels of production of these tumor antigen protein in both cancer and corresponding normal cells. Dr. Polakis further states that in approximately 80% of our observations we have found that increases in the level of a particular mRNA correlates with changes in the level of protein expressed from that mRNA when human tumor cells are compared with their corresponding normal cells. Dr. Polakis does not provide any information about the correlation between the level of mRNA and the level of protein of SEQ ID NO: 6 in any particular cells including cancer and normal uterine cells. Dr. Polakis does not provide any information that the antibodies to 30 of the tumor antigen include the antibody to the tumor antigen of SEQ ID NO: 6. Therefore, the Declaration, Dr. Polakis would not convince one of ordinary skill in the art having a reasonable expectation of success to use the method of binding an antibody to a human uterine cell that expresses a protein shown as SEQ ID NO: 6 without undue experimentation.

Therefore, NO claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

KAREN A. CANELLA PH.D
PRIMARY EXAMINER